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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/470,489	06/06/95	MONTAGNIER	L 2356.0014-09

FINNEGAN HENDERSON FARABOW  
GARRETT AND DUNNER  
1300 I STREET NW  
WASHINGTON DC 20005-3315

HM12/0607

EXAMINER	
PARKIN, J	
ART UNIT	PAPER NUMBER
1648	27

DATE MAILED: 06/07/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
**08/470,489**

Applicant(s)  
**Montagnier et al.**

Examiner  
**Jeffrey S. Parkin, Ph.D.**

Group Art Unit  
**1648**



☒ Responsive to communication(s) filed on 17 Mar 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 90-109 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 90-109 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Serial No.: 08/470,489  
Applicants: Montagnier et al.

Docket No.: 2356.0014-09  
Filing Date: 06/06/95

## Response to Amendment

### *Status of the Claims*

1. Acknowledgement is hereby made of the Amendment submitted 17 March, 1999, wherein claims 72-89 were canceled without prejudice or disclaimer and new claims 90-109 submitted. Claims 90-109 are pending in the instant application.

5

### *35 U.S.C. § 112, First Paragraph*

2. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

10       The specification shall contain a written description of the  
invention, and of the manner and process of making and using it, in  
such full, clear, concise, and exact terms as to enable any person  
skilled in the art to which it pertains, or with which it is most  
nearly connected, to make and use the same and shall set forth the  
best mode contemplated by the inventor of carrying out his  
15       invention.

3. Newly submitted claims 90-109 are rejected under 35 U.S.C. §  
112, first paragraph, as containing subject matter which was not  
described in the specification in such a way as to reasonably  
20       convey to one skilled in the relevant art that the inventor(s), at  
the time the application was filed, had possession of the claimed  
invention. *In re Rasmussen*, 650 F.2d 1212, 211 U.S.P.Q. 323  
(C.C.P.A. 1981). *In re Wertheim*, 541 F.2d 257, 191 U.S.P.Q. 90  
(C.C.P.A. 1976). The claims are directed toward methods of  
25       detecting HIV-2 nucleic acids employing HIV-2 specific probes that  
are capable of hybridizing to said nucleic acids under the recited  
melting temperatures, or methods of preparing said probes. As  
previously noted, the claims reasonably encompass probes that are  
capable of hybridizing to **any** region of the HIV-2 genome including  
30       the 5' and 3' long terminal repeats (LTRs), untranslated regions,  
and *gag*, *pol*, *env*, *vif*, *vpr*, *vpx*, *tat*, *rev*, and *nef* coding regions

(see Fields et al. (1990) for a review of the genomic organization of the human and simian immunodeficiency viruses). However, **the disclosure only provides a limited number of sub-genomic HIV-2 molecular cDNA clones** (refer to pages 23, 25, 26, 28, 37, and 62).

5 Specifically, the following clones were described: **E2, 27-5, 35-3, 4.6, 4.7, and 4.8**. Moreover, the disclosure fails to provide sufficient guidance pertaining to the nucleotide sequence of the inserts contained within these clones with the exception of three sequences (e.g., the **U3/R** region of the LTR, **gag**, and **pol** genes  
10 described on pages 56-61 and Figures 6 and 7). Furthermore, the disclosure fails to provide sufficient guidance pertaining to the nucleotide sequence of any given probe and the hybridization parameters that should be employed. The melting temperature of any  
15 given hybridization reaction is influenced by several elements including, inter alia, the molar fraction of G/C residues in the probe. However, the disclosure fails to provide any guidance pertaining to any of these parameters. The disclosure also fails to provide support for the use of the claimed probes under the  
20 claimed conditions. Melting temperatures are only disclosed in reference to hybridization reactions involving HIV-1 probes. Thus, the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

Applicants traverse and submit that molecular clones are disclosed that encompass the entire HIV-2<sub>ROD</sub> genome. While these  
25 clones may encompass the complete genome, nevertheless, complete nucleotide sequence data was not provided for the complete proviral genome. Moreover, the disclosure fails to describe the probes and hybridization conditions encompass by the claim language. Applicants further submit that the disclosure describes a "vast  
30 number" of nucleic acid molecules and provide legal precedence suggesting that every species need not be disclosed in the

application (*In re Angstadt*, 537 F.2d 498, 502-503, 190 U.S.P.Q. 214, 218 (C.C.P.A. 1976); *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997)). These arguments are not persuasive either. As noted in the preceding paragraph, the disclosure does not teach a "vast number" of nucleic acid probes, but rather discloses a limited number of sub-genomic clones which have been molecularly characterized to different extents. The disclosure does not provide any guidance pertaining to the identification, isolation, preparation, and use of HIV-2-specific nucleic acid probes under the claimed hybridization conditions. Moreover, legal precedence supports the Examiner's position. In the *Eli Lilly and Co.* decision the court noted that satisfaction of the written description requirement for nucleic acids (i.e., cDNAs) requires disclosure of the nucleotide sequence that contributes to the claimed molecule's structure and function. The court also noted that the description of generic cloning methods and/or a single species does not constitute an adequate written description of the nucleic acids *per se*. Concerning amino acid sequence disclosures, the court noted that the disclosure of an amino acid sequence does not provide sufficient written description for the claimed nucleic acids. This court, citing *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 U.S.P.Q.2d 1601, 1606 (Fed. Cir. 1993), emphasized that an adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 U.S.P.Q.2d at 1606.

It was further emphasized that prophetic examples and generalized

5 methods for preparing nucleic acids, which may be enabling for nucleic acid claims, do not meet the requirements pertaining to written description, since they do not provide any substantive structural/functional guidance. Applicants further argue that sufficient guidance is provided for the claimed invention since reference is made to the melting temperatures of the probe employed. As noted above, this vague reference fails to adequately describe the precise nucleic acid probe contemplated by applicants.

10 ***Finality of Office Action***

4. Applicants' amendment necessitated any and all new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

15 **A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.**

25 ***Correspondence***

30 5. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be

5 directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

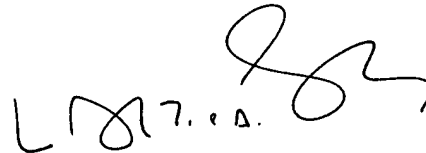
10 6. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Chris Eisenschenk, J.D., Ph.D., can be reached at (703) 308-0452. Any inquiry of a general nature or  
15 relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.  
Patent Examiner  
Art Unit 1648

15 January, 1999



LAURIE SCHEINER  
PRIMARY EXAMINER